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TOWNSEND and TOWNSEND and CREW LLP

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PATENT
Attorney Docket No. 021872-001900US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

ZIA YASSINZADEH

Application No.: 10/821,633

Filed: April 9, 2004

For: DEVICE AND METHOD FOR SEALING BLOOD VESSELS

Confirmation No. 9024

Examiner: Dang, Phong Son H

Technology Center/Art Unit: 3773

APPELLANTS' BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Further to the Notice of Appeal mailed on May 4, 2010, for the above-referenced application, Appellants submit this Brief on Appeal.

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1. REAL PARTY IN INTEREST

All right, title and interest in the subject invention and application was assigned to Cardiva Medical, Inc. having offices at 888 W. Maude Avenue, Sunnyvale, California 94085. The title is subject to a security interest held by Comerica Bank, a Texas Banking Association. Cardiva Medical, Inc is the Real Party in Interest.

2. RELATED APPEALS AND INTERFERENCES

No other appeals or interferences are known which will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1, 3-5, 7-11, 14, and 17-21 are currently pending. Claims 2, 6, 12-13, 15-16, and 22-67 have been previously canceled. Current pending claims 1, 5, 8, 10-11, and 17 were rejected under 35 U.S.C. § 102(b), and claims 3-4, 7, 9, 14, and 18-21 were rejected under 35 U.S.C. § 103(a). Currently pending claims 1, 3-5, 7-11, 14, and 17-21 are the subject of this appeal. No other claims are pending.

4. STATUS OF AMENDMENTS

No amendments to the claims were filed subsequent to the Final Office Action mailed on November 5, 2009. A response to the Final Office Action was filed on December 30, 2009 requesting reexamination and reconsideration of the final rejection. In an Advisory Action dated January 19, 2010, the Examiner entered the response and stated the claims were not in condition for allowance. A copy of all pending claims involved in the appeal is provided in the Claims Appendix, attached hereto.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides methods and kits for complete hemostasis of a puncture site in a body lumen, particularly blood vessels of the human body (page 3, lines 4-6). The methods comprise using a locating member to position a compression member a predetermined distance proximal from the wall of the blood vessel to compress tissue against the

puncture site to achieve hemostasis (page 3, lines 18-32; page 4, lines 1-4). Unless otherwise noted, all page and line numbers herein refer to the original text of Application No. 10/821,633, as filed on April 9, 2004.

Independent claim 1 recites a method for hemostasis of a puncture site in a blood vessel (page 6, lines 1-2; Figs. 8A-8G). The method comprises providing and inserting a locating member through a sheath so that an expansible member of the locating member enters the blood vessel (page 14, lines 10-15; Figs. 8A-8B), expanding an expansible member of the locating member and drawing the locating member proximally to cover the puncture site (page 14, lines 16-24; Fig. 8C), removing the sheath while leaving the locating member in place (page 14, lines 16-24; Fig. 8C), providing and advancing a tubular compression member over the locating member so that a compression element of the compression member is located at a predetermined distance proximal from the wall of the blood vessel (page 14, lines 27-31; Fig. 8D), and expanding the compression element to compress subcutaneous tissue over the puncture site to promote hemostasis (page 14, lines 31-33; Fig. 8E). The compression element is located at a predetermined site proximal from the wall of the blood vessel to define a tissue compression region (page 14, lines 30-33, Fig. 8E-8F). Expanding the compression element above the blood vessel wall applies pressure against the subcutaneous tissue (page 14, lines 30-33, Fig. 8E-8F) and is left in place until hemostasis has been achieved (page 15, lines 3-6).

Dependent claim 3 recites the method of claim 1 where the predetermined distance is in a range from about 0.05 inch to about 0.5 inch (page 4, lines 25-27).

Dependent claim 4 recites the method of claim 3 where the predetermined distance is in a range from about 0.2 inch to about 0.3 inch (page 4, lines 25-28).

Dependent claim 5 recites the method of claim 1 where the expansible tissue compression element on the compression member comprises a balloon (page 3, lines 22-23).

Dependent claim 7 recites the method of claim 1 where expanding comprises inflating a superior aspect of the balloon greater than its inferior aspect (page 7, lines 1-2).

Dependent claim 8 recites the method of claim 1 where expanding comprises inflating a distal face of the balloon at an angle to the compression member similar to an angle formed between the compression member and the blood vessel (page 7, lines 6-8).

Dependent claim 9 recites the method of claim 1 where expanding comprises inflating the balloon to a deployed configuration comprising a conical shape (page 7, lines 8-9).

Dependent claim 10 recites the method of claim 1 where expanding comprises unfolding concentric folds of the balloon (page 7, lines 9-10).

Dependent claim 11 recites the method of claim 1 where expanding comprises inflating the balloon to a deployed configuration having a concave distal end (page 7, lines 9-11).

Dependent claim 14 recites the method of claim 1 where the expansible member on the locating member is expanded to an expanded configuration within the blood vessel having a diameter in a range from about 0.05 inch to about 0.5 inch (page 7, lines 16-17).

Dependent claim 17 recites the method of claim 1, further comprising contracting and withdrawing the locating member while the compression member remains in place (page 15, lines 1-5).

Dependent claim 18 recites the method of claim 1, further comprising imaging the expansible element during positioning (page 6, lines 13-14).

Dependent claim 19 recites the method of claim 1, further comprising delivering radio frequency energy, ultrasound energy, or microwave energy to the puncture site (page 6, lines 14-15).

Dependent claim 20 recites the method of claim 1, further comprising delivering a clot promoting agent or anti-infection agent to the puncture site (page 6, lines 14-15).

Dependent claim 21 recites a kit comprising a compression member and instructions to use the compression member for hemostasis of a puncture site in a blood vessel according to claim 1 (page 14, lines 10-33; page 15, lines 1-5).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1, 5, 8, 10-11, and 17 were properly rejected under 35 U.S.C. 102(b) as being anticipated by Zucker (US Patent Application Publication 2003/0055454).

Whether claims 3-4, 7, 9, 14, and 18-21 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Zucker (US Patent Application Publication 2003/0055454).

7. ARGUMENT

Rejections Under 35 U.S.C. § 102(b)

Claims 1, 5, 8, 10-11, and 17 under 35 U.S.C. 102(b) were rejected as being anticipated by US Patent Application Publication 2003/0055454 by Zucker (hereinafter "Zucker"). Appellants respectfully disagree for the following reasons.

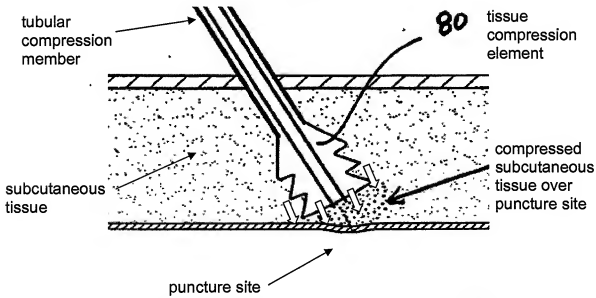
Anticipation of a claim under 35 USC § 102 requires that each and every element as set forth in the claim be described in a single prior art reference, and the identical invention must be shown in as complete detail as is contained in the claim. (M.P.E.P. § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added)).

Independent claim 1 reads as follows:

> *1. A method for hemostasis of a puncture site in a wall of a blood vessel at an end of a tissue tract having a sheath therein, the method comprising:*
> *providing a locating member having a proximal end, a distal end, and an expansible member disposed on the distal end thereof,*
> ***inserting the locating member through the sheath in the tissue tract** so that the expansible member on the locating member enters a lumen of the blood vessel;*
> *expanding the expansible member on the inserted locating member and drawing the inserted locating member proximally so that the expanded expansible member covers the puncture site in the vessel wall;*
> ***removing the sheath from the tissue tract while the inserted locating member remains in place;***
> ***providing a tubular compression member** having a proximal end, a distal end, a central passage between said proximal end and said distal end, and an expansible tissue compression element disposed over the distal portion thereof, and*
> ***advancing the tubular compression member over the inserted locating member after the sheath has been removed from the tissue tract** so that the locating member is received in the central passage of the tubular compression member and the expansible tissue **compression element is located within the tissue tract at a predetermined distance proximal from the wall of the blood vessel to define a tissue compression region**; and*
> ***expanding the expansible tissue compression element** within the tissue tract above the blood vessel wall **to apply pressure against subcutaneous tissue** and **to compress said tissue over the puncture site in the blood vessel wall to promote hemostasis**, wherein the expansible tissue compression element on the compression member is left in place until hemostasis has been achieved.* (emphasis added)

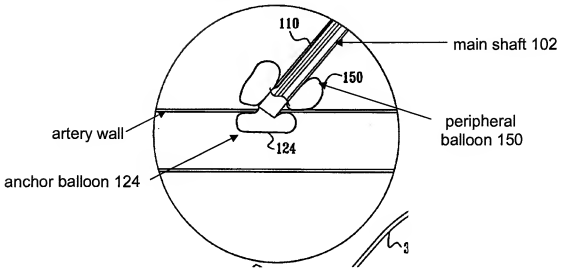
As shown in Figure 8F (annotated), the tubular compression member is advanced over the inserted locating member so that the tissue compression element is located a predetermined distance proximal from the wall of the blood vessel to define a tissue compression region. As the compression element is expanded above the blood vessel wall, the tissue compression element applies pressure against subcutaneous tissue and compresses the tissue over the puncture site, as illustrated for example in Figure 8F reproduced below (arrows added).

Fig. 8F



Zucker fails to disclose each and every element as set forth in the method of independent claim 1, particularly those elements of the claim that have been bolded. Zucker discloses a method for hemostasis of an artery by inserting a single device having both an inflatable anchor balloon and an inflatable peripheral balloon attached to its distal end (Zucker, Paragraph [0017]; Figs. 1 and 3B). The anchor balloon 124 (Fig. 3G reproduced below) is inflated to engage an inner wall surface of a wall of the artery and to position the peripheral balloon 150, which is then inflated above the outer surface of the artery wall. The inflated peripheral balloon surrounds and seals the aperture in the artery to allow hemostasis to occur (Paragraphs [0022] and [0024]; Figs. 3G-3I). The relationship between the anchor and peripheral balloons can be seen in a detail from Fig. 3G, reproduced below.

Fig. 3G (Zucker)



Zucker fails to disclose a separate locating member and tubular compression member. The anchor balloon 124 and peripheral balloon 150 of Zucker are distinguishable as they are not separate members; both balloons are attached to the distal region of main shaft 102 (Paragraphs [0017], [0037] and [0039]). Zucker also fails to disclose inserting a locating member through a sheath, removing the sheath while the inserted locating member stays in place, and advancing a compression member over the locating member after the sheath has been removed. Zucker discloses inserting main shaft 102 into the vessel through a sheath 304 (Paragraph [0017]). Since anchor balloon 124 and peripheral balloon 150 are both attached to the distal region of shaft 102, the device of Zucker cannot insert separate components, as recited in the method of claim 1. Zucker further fails to disclose advancing a tubular compression member so that the compression element is located a predetermined distance proximal from the wall of the blood vessel to define a tissue compression region. Neither does Zucker disclose expanding the compression element to apply pressure against subcutaneous tissue and to compress the tissue over the puncture site. The peripheral balloon of Zucker does not compress tissue in a tissue compression region, rather the balloon expands outwards as it lies adjacent an outer surface of the wall of the artery surrounding and sealing an aperture in the artery, as shown in Figure 3J reproduced below. Thus, the method of claim 1 is clearly distinguishable from the teachings of Zucker.

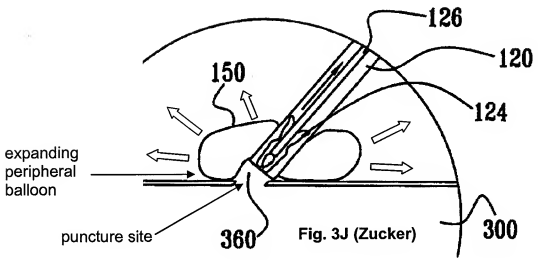
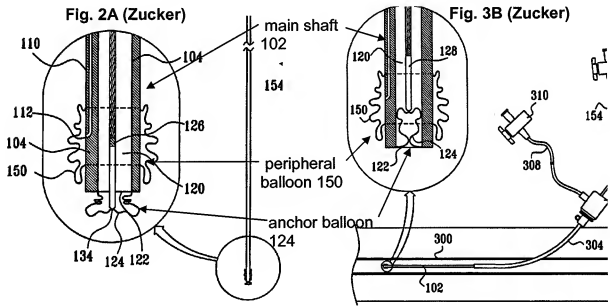


Fig. 3J (Zucker)

Moreover, claim 1 recites advancing the tubular compression member over the inserted locating member after the sheath has been removed from the tissue tract. Since peripheral balloon 150 and anchor balloon 124 are both attached to the distal region of main shaft 102, sheath 304 is clearly not withdrawn and cannot be withdrawn before inserting peripheral balloon 102. Nowhere does Zucker teach advancing a tubular compression member over a locating member as in claim 1. Furthermore, it is impossible to advance shaft 102 a distance proximal from the wall of the blood vessel as the claimed method does with a separate locating member.

The Examiner argues that Zucker describes a method utilizing "a locating member (ref. 128)" and a "tubular compression member (ref. 102)," as in the claimed method (Final Office Action, page 2). Applicants note that element 128 is an anchor balloon handle, which is irrelevant to the Examiner's argument. The Examiner probably meant to refer to element 126, which was incorrectly labeled as 128 on Figure 3B of Zucker. As disclosed in Zucker, element 126 is a rod and element 102 is a main shaft of the device, and neither element is capable of performing method steps as recited in claim 1. The anchor balloon handle 128 is secured to a proximal end of the main shaft 102 and fixed to rod 126, the distal end of which is attached to an inner surface of anchor balloon 124 (Paragraph [0037]; Fig. 2A). Thus, if one skilled in the art were to analogize the method and system of Zucker with those of the present invention, the main shaft 102 would most likely be considered the locating member of the

present invention. It is the main shaft 102 of Zucker that is placed through sheath 304 to position the anchor 124 against the inner wall of the blood vessel lumen. Anchor balloon 124 is attached to the distal ends of shaft 102 and rod 126. Proximally retracting rod 126 pulls anchor balloon 124 into main shaft 102, as illustrated in a detail of Figures 2A and 3B reproduced below (Paragraphs [0037] and [0039]). In contrast to the method of claim 1, anchor balloon 124 and peripheral balloon 150 cannot be separately inserted, nor can the peripheral balloon be separately advanced over the anchor balloon 124, as they are both attached to the distal region of shaft 102. Thus, Zucker fails to disclose the locating member and tubular tissue compression member of the method in claim 1.



Referring to Figure 3J, shown on page 9, the Examiner argues that "the medial portion of the balloon 150 and the exterior of the blood vessel define a predetermined space where 360 is." (Final Office Action, page 3). However, Zucker teaches surrounding and sealing the aperture with the peripheral balloon 102 (Paragraphs [0022] and [0024]), which would require direct contact with the artery wall. Applicants note that a balloon directly contacting the artery wall is clearly not located at a predetermined distance proximal from the wall of the blood vessel. Thus, Zucker fails to teach advancing a compression element to a predetermined distance proximal from the wall of the blood vessel to define a tissue compression region. Additionally,

the space 360, the region in which hemostasis occurs, is not analogous to a tissue compression region over the puncture of the claimed method. Thus, the method of Zucker is clearly distinguishable from that of the method in claim 1.

The Examiner then equates expanding the peripheral balloon 150 against an artery wall to seal an aperture, as disclosed in Zucker, with expanding a compression element to apply pressure to subcutaneous tissue compressing the tissue over the puncture site, as in the claimed method (Final Office Action, page 3). Applicants maintain, however, that the balloon 150 of Zucker is incapable of performing this function as it is positioned at the distal end of the device adjacent the artery wall. As illustrated in Figure 3J of Zucker on page 9, however, the expanding peripheral balloon 150 spreads tissue outward as it expands leaving a space over the puncture site for hemostasis to occur (vector arrows added). In contrast, the compression element of the claimed method, when expanded, compresses subcutaneous tissue in the tissue compression region over the puncture site. Applicants maintain that the peripheral balloon of Zucker does not and cannot apply pressure to subcutaneous tissue to compress the subcutaneous tissue over the puncture site.

For the foregoing reasons, Appellants respectfully submit that the Examiner has failed to establish anticipation by Zucker, since Zucker fails to teach the steps of claim 1 and fails to disclose a device capable of performing the claimed method steps. Accordingly, the rejection of claim 1 under 35 U.S.C. 102(b) should be reversed.

Dependent claims 5, 8, 10-11, and 17, which depend from independent claim 1, are allowable for at least the same reasons as claim 1, as well as on their own merits. Accordingly, Appellants request the rejections of claims 5, 8, 10-11, and 17 under 35 U.S.C. 102(b) be reversed.

Rejections Under 35 U.S.C. § 103(a)

The rejections of claims 3-4, 7, 9, 14, and 18-21 under 35 U.S.C. § 103(a) as being obvious over Zucker should be reversed. Appellants believe that the Examiner has not established *prima facie* obviousness under 35 U.S.C. § 103(a) and MPEP §§ 2142 and 2143, and therefore respectfully traverses these rejections for the reasons discussed below.

The rejections of dependent claims 3-4, 7, 9, 14, and 18-21 are premised on Zucker disclosing all the elements of claim 1. As discussed above, Zucker fails to teach all the elements of method claim 1. Therefore, the claim rejections are based on a flawed premise and cannot be maintained.

Moreover, regarding the rejections of claims 3-4, 7, 9 and 14, Applicants submit that there would be no reason to modify Zucker as recited in the claimed methods. Since the peripheral balloon of Zucker expands outward from a location adjacent to a vessel wall to delimit a stagnation area for coagulation (Paragraph [0050]), it would be counterintuitive to locate the peripheral balloon a distance away from the vessel wall, as in claims 3 and 4. Likewise, there would be no reason for one to modify the shape or diameter of the peripheral balloon, as described in claims 7, 9 and 14. In fact, locating the balloon a distance away from the vessel wall or modifying the balloon into the claimed shapes could prevent the balloon from surrounding the aperture failing to delimit a stagnant area for coagulation, thereby rendering the device of Zucker useless for its intended purpose. Thus, it would not be obvious to modify the methods of Zucker as in the claimed methods.

For the foregoing reasons, Appellants respectfully submit that a *prima facie* case of obviousness under 35 U.S.C. § 103(a) has not been met. The Examiner's rejections under Zucker have failed to satisfy the threshold requirement that the cited references teach or suggest all elements of the claimed invention, as well as a reason for so modifying the reference. Accordingly, the rejections of claims 3-4, 7, 9, 14, and 18-21 under 35 U.S.C. § 103(a) should be reversed and the claims allowed.

8. CONCLUSION

For these reasons, it is respectfully submitted that the rejection should be reversed.

Respectfully submitted,

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9. CLAIMS APPENDIX

1. (Previously Presented) A method for hemostasis of a puncture site in a wall of a blood vessel at an end of a tissue tract having a sheath therein, the method comprising:

providing a locating member having a proximal end, a distal end, and an expansible member disposed on the distal end thereof,

inserting the locating member through the sheath in the tissue tract so that the expansible member on the locating member enters a lumen of the blood vessel;

expanding the expansible member on the inserted locating member and drawing the inserted locating member proximally so that the expanded expansible member covers the puncture site in the vessel wall;

removing the sheath from the tissue tract while the inserted locating member remains in place;

providing a tubular compression member having a proximal end, a distal end, a central passage between said proximal end and said distal end, and an expansible tissue compression element disposed over the distal portion thereof, and

advancing the tubular compression member over the inserted locating member after the sheath has been removed from the tissue tract so that the locating member is received in the central passage of the tubular compression member and the expansible tissue compression element is located within the tissue tract at a predetermined distance proximal from the wall of the blood vessel to define a tissue compression region; and

expanding the expansible tissue compression element within the tissue tract above the blood vessel wall to apply pressure against subcutaneous tissue and to compress said tissue over the puncture site in the blood vessel wall to promote hemostasis, wherein the expansible tissue compression element on the compression member is left in place until hemostasis has been achieved.

2. (Canceled)

3. (Original) The method of claim 1, wherein the predetermined distance is in a range from about 0.05 inch to about 0.5 inch.

4. (Original) The method of claim 3, wherein the predetermined distance is in a range from about 0.2 inch to about 0.3 inch.

5. (Previously Presented) The method of claim 1, wherein the expansible tissue compression element on the compression member comprises a balloon.

6. (Canceled)

7. (Previously Presented) The method of claim 1, wherein expanding comprises inflating a superior aspect of the balloon greater than an inferior aspect of the balloon.

8. (Previously Presented) The method of claim 1, wherein expanding comprises inflating a distal face of the balloon at an angle to the compression member similar to an angle formed between the compression member and the blood vessel.

9. (Previously Presented) The method of claim 1, wherein expanding comprises inflating the balloon to a deployed configuration comprising a conical shape.

10. (Previously Presented) The method of claim 1, wherein expanding comprises unfolding concentric folds of the balloon.

11. (Previously Presented) The method of claim 1, wherein expanding comprises inflating the balloon to a deployed configuration having a concave distal end.

12.-13. (Canceled)

14. (Previously Presented) The method of claim 1, wherein the expansible member on the locating member is expanded to an expanded configuration within the blood vessel having a diameter in a range from about 0.05 inch to about 0.5 inch.

15.-16. (Canceled)

17. (Previously Presented) The method of claim 1, further comprising contracting and withdrawing the locating member while the compression member remains in place.

18. (Original) The method of claim 1, further comprising imaging the expansible element during positioning.

19. (Original) The method of claim 1, further comprising delivering radio frequency energy, ultrasound energy, or microwave energy to the puncture site.

20. (Original) The method of claim 1, further comprising delivering a clot promoting agent or anti-infection agent to the puncture site.

21. (Original) A kit comprising:

a compression member; and

instructions to use the compression member for hemostasis of a puncture site in a blood vessel according to claim 1.

22.-67. (Canceled)

10. EVIDENCE APPENDIX

11. RELATED PROCEEDINGS APPENDIX